

### **Remarks**

Claims 1 to 5 and 12 to 19 are withdrawn from further consideration. Claims 20 to 31 are under examination. Claims 32 and 33 are new and have been added for the sole purpose to clarify what is meant by the reference to “blood sample” in claims 20 and 27, respectively. Support can be found, e.g., on page 3, penultimate and last paragraph of the specification and page 7 of the specification.

### **Claim Rejections – 35 USC §112,2<sup>nd</sup> paragraph**

On page 3, the Office continued to reject claims 20 to 26 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office noted on page 3 of the Action that amending claim 20 to indicate that the contacting step is performed under conditions permitting binding of the auto-antibodies to the peptides (similar to the wording provided in new claim 27) is one way of obviating the rejection.

In response, applicants have amended claim 20 accordingly.

### **Claim Rejections – 35 USC §112,1<sup>st</sup> paragraph (enablement)**

Also on page 3, the Office continued to reject claims 20 to 29 and 31 under 35 USC §112, first paragraph, stating that the specification does not enable the person skilled in the art to which it pertains, or with which it most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Office expressed the opinion that the specified peptides are not representative of the scope of the generic claim (claim 20) which recites a peptide of an AT1 receptor comprising 5 to 30 amino acids of loop II of the receptor or functional analogs thereof.

In response, applicants have amended claim 20 to remove the reference to

“functional analogs thereof” and have specified peptides consisting essentially of at least one of amino acid sequences SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 or SEQ ID NO: 4.

The Office also responded to applicants’ argument that Example 3 and Figure 2 show that all of the five specifically recited peptides are functional.

The Office expressed the opinion that Figure 2 clearly shows that ENTNIT and the three other peptides mentioned in Figure 2 were ineffective. ENTNIT has been deleted from the claims. The other three peptides shown in the Figure (VFFIEN, ITVCAF, QNSTLPI) are not being claimed.

Example III shows in Table 1 that SEQ ID NOs: 1, 3 and 4 were able to neutralize the antibodies. The specification states:

“In preeclampsia patients, the agonistic effect of the antibodies achieved via the AT1 receptor was only neutralized by the peptide AFHYESQ. This epitope has a special importance in this disease, as it was identified in all the patients examined. The functional-analog peptides SHFYQTR and GYYFDTN were also in a position to neutralize the antibodies, Tab I.” (*emphasis added*)

SHFYQTR and GYYFDTN are SEQ ID NOs: 3 and 4, respectively.

While SEQ ID NO: 2 is not specifically mentioned in this example, the sequence is mentioned in the context of preeclampsia diagnosis, e.g., on page 4, last full paragraph of the specification. It is also mentioned to be a functional analog peptide of SEQ ID NO: 1 (see page 4, first paragraph).

Applicants have also amended claim 20 to recite an *in vitro* usage, thus, without admitting to the correctness of the Office’s analysis, rendering the respective rejection moot.

On page 6, the Office also notes that page 7 shows that SEQ ID No: 1 is able to bind and inhibit the effects of autoantibodies against the angiotensin AT<sub>1</sub> receptor,

obtained from the "gamma-globulin fraction of the serum of preeclampsia patients."

Consistent with the disclosure as noted by the Office, applicants have amended the term "a body fluid" in claim 20 to "a blood sample" The claim clarifies that the "blood sample" is from "a patient suspected of having preeclampsia" conforming well with the recited teachings of page 7. Also consistent with page 7 of the specification, claims 32 and 33 have been added to clarify what the reference to "blood sample" encompasses.

**Claim Rejections – 35 USC §112, 1<sup>st</sup> paragraph (written description)**

On page 7, the Office continued to reject claims 20 to 29 and 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Office found applicants previous argument not persuasive since claim 20 still recited "or functional analogs thereof."

Applicants have amended claim 20 to eliminate the reference to functional analogs.

With the above amendments, applicants submit that all rejections have been addressed and that the case is now in condition for allowance.

The Commissioner is authorized to charge or credit undersign's deposit account 50-3135 for any payments that may become due with this response.

Respectfully submitted,

By: /Joyce v. Natzmer/  
Joyce von Natzmer  
Registration No. 48,120  
**Customer No. 46002**  
Telephone: (301) 657-1282

January 4, 2010